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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/590,940

09/26/2006

Domenico Geraci

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23117 7590 05/26/2009  
NIXON & VANDERHYE, PC  
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EXAMINER

ROONEY, NORA MAUREEN

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

05/26/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/590,940	<b>Applicant(s)</b> GERACI, DOMENICO	
	<b>Examiner</b> NORA M. ROONEY	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 23-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 23-44 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Election/Restrictions***

1. Applicant's amendment filed on 08/28/2006 is acknowledged.
2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

3. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 23-28, 33-39 and 44, directed to a fusion protein characterized in that it comprises the amino acid sequences of different allergens belonging to the non-specific Lipid Transfer Protein (ns-LTPs) family, in that said sequences lack one or more of the four disulphide bridges present in the sequences of the wild type allergens, at least one in the amino terminal region comprised between amino acid residues 1 and 30 and in that said sequences maintain essentially the same length as the sequences of wild type allergens, pharmaceutical compositions thereof and methods of preparing a pharmaceutical composition.

II. Claims 29-32 and 40-43, directed to nucleic acid encoding and a method of producing a fusion protein characterized in that it comprises the amino acid sequences of different allergens belonging to the non-specific Lipid Transfer Protein (ns-LTPs) family, in that said sequences lack one or more of the four disulphide bridges present in the sequences of the wild type

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allergens, at least one in the amino terminal region comprised between amino acid residues 1 and 30 and in that said sequences maintain essentially the same length as the sequences of wild type allergens and expression systems and host cells thereof.

4. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I-II lack unity of invention because even though the inventions of these groups require the technical feature of a fusion protein, this technical feature is not a special technical feature as it does not define the contribution over the prior art of WO 02/20790 (IDS filed on 08/28/2006) in view of U.S. Patent Publication 2006/0155116 (PTO-892; Reference A).

WO 02/20790 teaches the Parj 1 and Parj 2 non-specific Lipid Transfer Proteins (ns-LTPs) lacking one or more of the four disulphide bridges present in the sequences of the wild type allergens, at least one in the amino terminal region comprised between amino acid residues 1 and 30 and in that said sequence maintains essentially the same length as the sequences of wild type allergens, nucleic acids encoding the allergens, pharmaceutical compositions comprising one or both of the allergens and methods of preparing the proteins and pharmaceutical compositions (In particular, page 7, line 36 to page 8, line 6, whole document). The reference also teaches that Par j1 and Par j 2 may be administered together in a pharmaceutical composition and that the reference encompasses any variant which include substitutions, deletions or insertions to the Par

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j 1 and Par j2 sequences resulting in a lack of at least one disulfide bridge (In particular, claim 25, page 14, lines 17-page 15, line 2)

The claimed invention differs from the prior art in the recitation of a fusion protein comprising the amino acid sequences of different allergens belonging to non-specific Lipid Transfer Proteins (ns-LTPs) family.

U.S. Patent Publication 2006/0155116 teaches fusion proteins of hypoallergenic Par j1 and Par j2 allergens mutated in the loop 1 region which comprises IgE epitopes owing to disulfide bridge formation in that area and pharmaceutical compositions thereof (In particular, paragraphs[0006], [0015], [0022], whole document)

It would have been obvious to one of ordinary skill in the art at the time of invention to combine the mutant Par j1 and Par j2 proteins taught by WO 02/20790 into a single fusion protein as taught by U.S. Patent Publication 2006/0155116 because WO 02/20790 teaches that Par j1 and Par j 2 may be administered together and that variants which include substitutions, deletions or insertions to the Par j 1 and Par j2 sequences resulting in a lack of at least one disulfide bridge are encompassed. U.S. Patent Publication 2006/0155116 teaches that Par j1 and Parj 2 may be combined in a single fusion protein and used in pharmaceutical compositions.

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention. The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937.

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The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 20, 2009

Nora M. Rooney

Patent Examiner

Technology Center 1600

/Nora M Rooney/

Examiner, Art Unit 1644